

0015 Efficacy of Fluoride Varnish in Preventing Early Childhood Caries

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Early childhood caries (ECC) is prevalent in many underserved populations. Fluoride varnish (FV) has been shown to be effective in preventing caries in school-age children with differing effectiveness in preschool children.

Objectives: To determine the efficacy of FV (Duraphat, 5% Na F, Colgate) plus parental counseling versus counseling alone in preventing ECC in young children, a 2-yr randomized clinical trial was conducted. **Methods:** Initially 376 caries-free children with at least 4 maxillary teeth, mean age \pm SD 1.8 \pm 0.6 years, were randomized to 3 study arms. All families received oral health counseling; one group received no FV (0FV), one was assigned to receive FV 1x/yr (2FV), the other 2x/yr (4FV). San Francisco study locations were the Chinatown Public Health Center and SF General Hospital, which primarily served low-income, high caries-risk, Chinese and Hispanic populations, respectively. Parental (or caregiver) counseling was provided as appropriate to the child's age in Chinese, Spanish or English. The dental examiner was masked to treatment group.

Results: 253 (67%) children completed the study and 280 (75%) had 1-yr or 2-yr clinical exams. Because of an unexpected protocol deviation, not all children received active FV during part of the study, resulting in 75% of children in 2FV group receiving 1 active FV application; 49% in 4FV group receiving 2. Intent-to-treat analyses of the last exam showed the percentage of children with caries experience, d2-4fs>0 by intended group were: 42% (0FV), 25% (2FV), 16% (4FV), p<0.01; with d1-4fs>0 were: 64% (0FV), 47% (2FV), 37% (4FV), p<0.01. When proportions with d2-4fs>0 and d1-4fs>0 were analyzed according to number of actual active FV applications received, there was a strong dose-response effect (d2-4fs>0 and d1-4fs>0, both p <0.01). There were no adverse health or safety events reported. **Conclusion:** Fluoride varnish and parental counseling are efficacious in preventing ECC. NIH/NIDCR P60DE13058 U54DE142501

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